

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.


Substitution for Form 1449/A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.	
		<b>Complete If Known</b>	
Applicant Number	09/943,138	Filing Date	August 30, 2001
First Named Inventor	Wallace K. DYER	Group Art Unit	1639
Examiner Name	Epperson, Jon	Attorney Docket Number	04118/0104 (43076/250892)

## U.S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

[illegible]

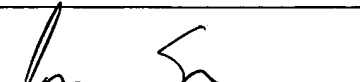
Examiner Signature		Date Considered	7/12/03
-----------------------	---	--------------------	---------

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449/A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Use as many sheets as necessary		Application Number	09/943,138
		Filing Date	August 30, 2001
		First Named Inventor	Wallace K. Dyer
		Group Art Unit	1614
		Examiner Name	
		Attorney Docket Number	04118-0104 (43076-257892)
Sheet 1 of 4			

OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
JE		Wen, O., "Response to Subdermal Implantation of Textured Microimplants in Humans," <i>Aesthetic Plastic Surgery</i> , Vol. 16, pp. 227-230 (1992)	✓
		Beisang, A., <i>et al.</i> , "Mammalian Response to Subdermal Implantation of Textured Microimplants," <i>Aesthetic Plastic Surgery</i> , Vol. 16, pp. 83-90 (1992)	✓
		Blecher, L., <i>et al.</i> , "Polyvinylpyrrolidone," <u>Handbook of Water Soluble Gums and Resins</u> , McGraw-Hill, Chapter 21, pp. 1-21 (1980)	✓
		Boros, D., <i>et al.</i> , "Granulomatous Inflammations," <i>Prog. Allergy</i> , Vol. 24, pp. 183-267 (1978)	✓
		Boss, W., <i>et al.</i> , "Isolagen," <u>Tissue Augmentation in Clinical Practice: Procedures and Techniques</u> , Marcel Dekker, Chapter 17, pp. 335-347 (1998)	✓
		Choe, K., <i>et al.</i> , "Chin Augmentation," <i>Facial Plastic Surgery</i> , Vol. 16, No. 1 (2000)	✓
		Costantino, P., <i>et al.</i> , "Synthetic Biomaterials in Facial Plastic and Reconstructive Surgery," <i>Facial Plastic Surgery</i> , Vol. 9, No. 1 (1993)	✓
		Dewan, P.A., <i>et al.</i> , "Histological Response to Injected Polytef and Bioplastique in a Rat Model," <i>British Journal of Urology</i> , Vol. 73, pp. 370-376 (1994)	✓
		Dewan, P.A., <i>et al.</i> , "Long-term Histological Response to Subcutaneously Injected Polytef and Bioplastique in a Rat Model," <i>British Journal of Urology</i> , Vol. 76, pp. 161-164 (1995)	✓
		Ersek, R., <i>et al.</i> , "Bioplastique <sup>TM</sup> : A New Biphasic Polymer for Minimally Invasive Injection Implantation," <i>Aesthetic Plastic Surgery</i> , Vol. 16, pp. 59-65 (1992)	✓
		Ersek, R., "Prostheses for Breast Augmentation," <i>Travis County Medical Society Journal</i> , pp. 8-10 (1989)	✓
		Ersek, R., <i>et al.</i> , "Bioplastique: A New Textured Copolymer Microparticle Promises Permanence in Soft-tissue Augmentation," <i>Plastic and Reconstructive Surgery</i> , Vol. 87, pp. 693-702 (1991)	✓

Examiner Signature		Date Considered	7/1/03
--------------------	---	-----------------	--------

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.RECEIVED  
MAY 10 2002  
FBI CENTER 1600/2910

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Form 1449/A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	09/943,138
		Filing Date	August 30, 2001
		First Named Inventor	Wallace K. Dyer
		Group Art Unit	1614
		Examiner Name	
		Attorney Docket Number	04118-0104 (43076-257892)
Sheet 2	of 4		

OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
JE		Ersek, R., "Bioplastique: Specific Technical Advice on its Use and Possible Complications," <i>Aesthetic Plastic Surgery</i> , Vol. 16, pp. 67-68 (1992)	✓
		Ersek, R., <i>et al.</i> , "Bioplastique at 6 Years: Clinical Outcome Studies," <i>Plastic and Reconstructive Surgery</i> , Vol. 100, No. 6, pp. 1570-1574 (1997)	✓
		Ersek, R., <i>et al.</i> , "A New Arteriovenous Shunt Design," <i>Amer. Soc. Int. Organs</i> , Vol. XV, pp. 267-271 (1969)	✓
		Ersek, R., <i>et al.</i> , "Chin Augmentation Using Minimally Invasive Technique and Bioplastique," <i>Plastic and Reconstructive Surgery</i> , Vol. 95, pp. 985-992 (1995)	✓
		Klock, J., <i>et al.</i> , "Detection, Pathogenesis, and Prevention of Damage to Human Granulocytes Caused by Interaction with Nylon Wool Fiber: Implications for Filtration Leukapheresis," <i>J. of Clinical Investigation</i> , Vol. 60, pp. 1183-1190 (1977)	✓
		Lemperle, G., <i>et al.</i> , "PMMA Microspheres (Artecoll) for Skin and Soft-Tissue Augmentation. Part II: Clinical Investigations," <i>Plastic and Reconstructive Surgery</i> , Vol. 96, pp. 627-634 (1995)	✓
		Levine, B., <i>et al.</i> , "The Current Status of Expanded Polytetrafluoroethylene (Gore-Tex) in Facial Plastic Surgery," <i>ENT - Ear, Nose &amp; Throat Journal</i> , Vol. 74, No. 10, pp. 681-684 (1995)	✓
		Maas, C., <i>et al.</i> , "Evaluation of Expanded Polytetrafluoroethylene as a Soft-Tissue Filling Substance: An Analysis of Design-Related Implant Behavior Using the Porcine Skin Model," <i>Plastic and Reconstructive Surgery</i> , Vol. 101, pp. 1307-1314 (1998)	✓
		Maas, C., <i>et al.</i> , "Expanded Polytetrafluoroethylene (Gore-Tex Soft-Tissue Patch) in Facial Augmentation," <i>Arch. Otolaryngol. Head Neck Surg.</i> , Vol. 119, pp. 1008-1014 (1993)	✓
		Merritt, K., <i>et al.</i> , "Implant Site Infection Rates with Porous and Dense Materials," <i>J. Biomedical Materials Research</i> , Vol. 13, pp. 101-108 (1979)	✓
		Mole, B., "The Use of Gore-Tex Implants in Aesthetic Surgery of the Face," <i>Plastic Reconstructive Surgery</i> , Vol. 90, No. 2, pp. 200-206 (1992)	✓
		Morehead, J.M., <i>et al.</i> , "Soft-Tissue Response to Synthetic Biomaterials," <i>Otolaryngologic Clinics of North America</i> , Vol. 27, pp. 195-201 (1994)	✓

Examiner Signature		Date Considered	7/14/03
--------------------	---	-----------------	---------

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449/A/PTO		<b>Completeness of Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Application Number</b>	09/943,138
		<b>Filing Date</b>	August 30, 2001
		<b>First Named Inventor</b>	Wallace K. Dyer
		<b>Group Art Unit</b>	1614
		<b>Examiner Name</b>	
		<b>Attorney Docket Number</b>	04118-0104 (43076-257892)
Sheet 1 of 4			

OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
JK		Nijhuis, P.H., <i>et al.</i> , "Perianal Injection of Polydimethylsiloxane (Bioplastique <sup>TM</sup> Implants) Paste in the Treatment of Soiling: Pilot Study in Rats to Determine Migratory Tendency and Locoregional Reaction," <i>Dis Colon Rectum</i> , Vol. 41, No. 5, pp. 624-629 (1998)
		Niechajev, I., "Lip Enhancement: Surgical Alternatives and Histologic Aspects," <i>Plastic and Reconstructive Surgery</i> , Vol. 105, No. 3, pp. 1173-1183 (1995)
		Piacquadio, D., <i>et al.</i> , "Evaluation of Hylan b Gel as a Soft-Tissue Augmentation Implant Material," <i>Journal of the American Academy of Dermatology</i> , Vol. 36, No. 4, pp. 544-549 (1997)
		Robinson, B.V., <i>et al.</i> , <u>PVP: A Critical Review of the Kinetics and Toxicology of Polyvinylpyrrolidone (Povidone)</u> , Lewis Publishers. (1990)
		Romo, T., <i>et al.</i> , "Use of Porous High-Density Polyethylene in Revision Rhinoplasty and in the Platyrhine Nose," <i>Aesthetic Plastic Surgery</i> , Vol. 22, pp. 211-221 (1998)
		Schoenrock, L.D., <i>et al.</i> , "Correction of Subcutaneous Facial Defects Using Gore-Tex," <i>Facial Plastic Surgery Clinics of North America</i> , Vol. 2, No. 3, pp. 373-388 (1994)
		Sclafani, A.P., <i>et al.</i> , "Biology and Chemistry of Facial Implants," <i>Facial Plastic Surgery</i> , Vol. 16, No. 1, pp. 3-6 (2000)
		Sclafani, A.P., <i>et al.</i> , "Clinical and Histologic Response of Subcutaneous Expanded Polytetrafluoroethylene (Gore-Tex) and Porous High-Density Polyethylene (Medpor) Implants to Acute and Early Infection," <i>Arch Otolaryngol Head Neck Surgery</i> , Vol. 123, pp. 328-336 (1997)
		Sclafani, A.P., <i>et al.</i> , "Injectable Fillers for Facial Soft Tissue Enhancement," <i>Facial Plastic Surgery</i> , Vol. 16, No. 1, pp. 29-34 (2000)
		Silver, F.H., <i>et al.</i> , "Biology of Synthetic Facial Implant Materials," <i>Facial Plastic Surgery Clinics of North America</i> , Vol. 2, No. 3, pp. 241-253 (1994)
		Simons, G., <i>et al.</i> , "Utilization of Injectable Microimplants in Aesthetic Facial Surgery," <i>Aesthetic Plastic Surgery</i> , Vol. 16, pp. 77-82 (1992)
		Smahel, J., "Tissue Reactions to Breast Implants Coated With Polyurethane," <i>Plastic Reconstructive Surgery</i> , Vol. 61, No. 1, pp. 80-85 (1978)

Examiner Signature	Date Considered
<i>[Signature]</i>	7/1/03

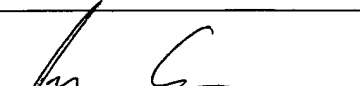
RECEIVED  
 MAY 10 2002  
 TELETYPE UNIT 1600/2200

Substitute for Form 1449/A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Application Number</b>	09/943,138
		<b>Filing Date</b>	August 30, 2001
		<b>First Named Inventor</b>	Wallace K. Dyer
		<b>Group Art Unit</b>	1614
		<b>Examiner Name</b>	
Sheet 4 of 4	<b>Attorney Docket Number</b>	04118-0104 (43076-25789)	

**OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS**

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published

Examiner Initials	Date	Item	T <sup>2</sup>
MA 17 2002		Staffel, G., <i>et al.</i> , "Nasal Implants," <i>Implants in Otolaryngology</i> , Vol. 28, No. 2, pp. 295-308 (1995)	/
		Stucker, F.J., <i>et al.</i> , "Use of Implantation in Facial Deformities," <i>Laryngoscope</i> , Vol. 87, pp. 1523-1528 (1977)	/
		Tang, L., <i>et al.</i> , "Inflammatory Responses to Biomaterials," <i>Am. J. Clin. Pathol.</i> , Vol. 103, pp. 466-471 (1995)	/
		Taylor, S. R., <i>et al.</i> , "Effect of Surface Texture on the Soft Tissue Response to Polymer Implants," Vol. 17, pp. 205-227 (1983)	/
		Tolleth, H., "Long Term Efficacy of Collagen," <i>Aesthetic Plastic Surgery</i> , Vol. 9, pp. 155-158 (1985)	/
		Watson, D., <i>et al.</i> , "Autologous Fibroblasts for Treatment of Facial Rhytids and Dermal Depressions: A Pilot Study," <i>Arch Facial Plast. Surg.</i> , Vol. 1, pp. 165-170 (1999)	/
		Whalen, R.L., <i>et al.</i> , "Connective Tissue Response to Movement at the Prosthesis/Tissue Interface," <i>Biocompatible Polymers, Metals and Composites</i> , Technomic, Chapter 42, pp. 953-974 (1983)	/
		Whear, N.M., <i>et al.</i> , "Post-operative Infection of Proplast Facial Implants," <i>British Journal of Oral &amp; Maxillofacial Surgery</i> , Vol. 31, pp.292-295 (1993)	/
		Zimmerli, W., <i>et al.</i> , "Pathogenesis of Foreign Body Infection: Description and Characteristics of an Animal Model," <i>The Journal of Infectious Diseases</i> , Vol. 146, No. 4, pp. 487-497 (1982)	/

Examiner Signature		Date Considered	7/1/03
--------------------	---	-----------------	--------